GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

November 8, 2006

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- FlexiView 8800 Mobile C-Arm
- OEC® Miniview 6800
- OEC® UroView 2800
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare has identified several intermittent potential safety issues that may occur with these products based upon feedback from some customers. The details and symptoms of these issues, as well as the associated interim or permanent solutions, are outlined below.

1. Navigation Tracking Inaccuracy:

Affected Products: OEC® FluoroTrak 9800 Plus

An issue has been discovered with the OEC® FluoroTrak 9800 Plus that could result in an incorrect position of instrumentation versus the displayed reference image. **This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.**

Permanent Solution:

GE OEC is currently investigating corrective solutions. When a corrective solution has been identified the GE OEC service team will contact your facility and arrange implementation of the corrective action.

Users are advised to stop using the system WITH NAVIGATION until this replacement has been successfully completed. OEC® FluoroTrak 9800 Plus system may be used as a standard C-Arm providing you review the other issues as listed below.

2. System Lock Up:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System

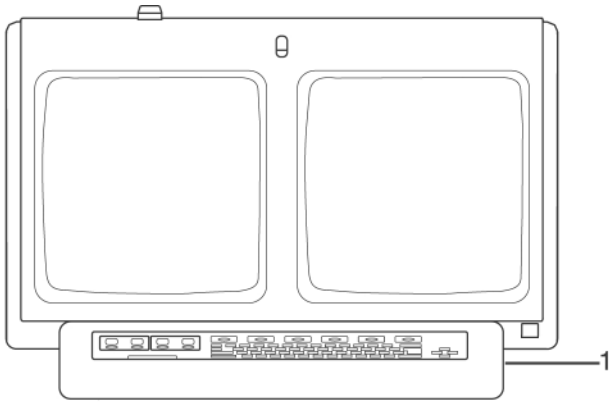
GEHC OEC has become aware of a potential problem with the above-indicated products where the C-arm may lock-up. Specifically, during system usage, the system may fail to function (produce live x-rays), and the collimators may close. In addition, the system display may indicate that the system is active (such as sound and/or light displays) when, in fact, the system is not producing live x-rays. The left monitor of the system will not update (no live fluoroscopy). There will be no radiation emission occurring despite the audible and visual indicators. If it is suspected that the system has emitted an uncommanded radiation exposure the user should contact GEHC to have the exposure logs reviewed to confirm if an exposure was made.

In critical clinical scenarios in which the C-arm is being used to make real-time therapeutic decisions or guide real-time interventions, a system lock-up may cause a procedural delay. Users should always be certain that the images shown on the Left Monitor are refreshing and are in fact live x-ray images (one indicator of this status is that the word "live" displayed on the screen).

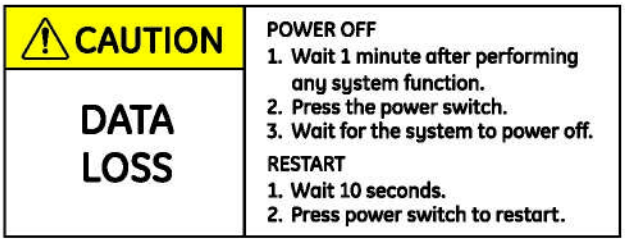
Interim Solution:

Should your OEC System experience a Lock-up, restarting (rebooting) the system should restore system functionality. The restarting (reboot) procedure for OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 will take less than 3 minutes. **Images saved prior to the system locking up will be restored and are retrievable. Images not saved prior to the system failure will not be restored.** At this time a corrective solution for the OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 is under investigation. Your facility will be notified as soon as a solution has been identified.

Instructions for rebooting (restarting) the system are located in the Operators Guide. **In addition enclosed is a sheet of supplemental stickers, including instruction for attachment, which demonstrates the restart steps. These stickers should be promptly attached to your system(s)as indicated below (suggest placement in location #1).**



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

3. Incorrect Image Display:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, OEC® Miniview 6800

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images, however, are labeled with the correct patient information, and may be located within another patient's file.

Interim Solution:

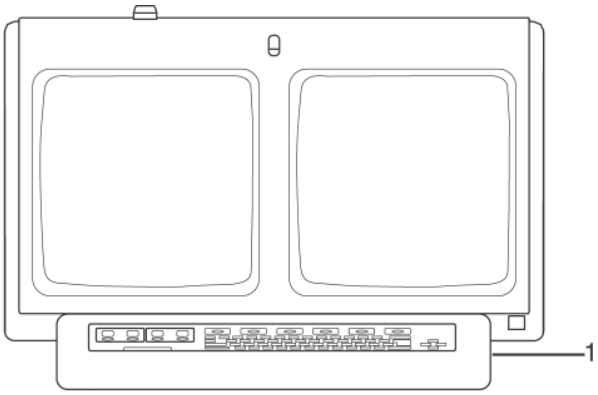
At this time a corrective software solution for the OEC 9800 Plus, OEC FlexiView 8800, OEC UroView 2800, and OEC MiniView 6800 is under investigation. Your facility will be notified as soon as a solution has been identified.

To reduce the occurrence of this issue users should follow the correct power down procedure.

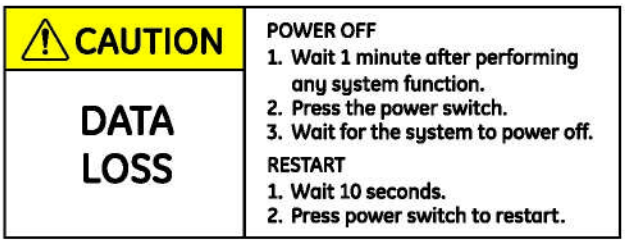
The power down procedure is also described in the Operators Guide and on the supplemental stickers enclosed with this notification.

The supplemental stickers should be installed on your system(s) promptly following the enclosed instructions and as indicated below (suggest placement in location #1).

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination being reviewed and contains the correct patient demographic information on the image itself until a comprehensive and permanent solution has been developed.



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
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2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

4. Incorrect Dose Area Product/Calculated Air Kerma in "Film Mode " and "Digital Spot Mode":

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800*MD* Motorized C-arm System

An issue has been reported that results in incorrect calculation, display and recording of patient dose while in film or digital spot mode. During a procedure, both the calculated Cumulative Air Kerma and the Air Kerma Rate can be observed on the live imaging monitor. This shows the AKR (air kerma rate) during fluoro exposures, and CAK (cumulative air kerma) after & between

fluoro acquisitions. Either during the procedure, or more typically, after the procedure, Cumulative Air Kerma and/or Dose Area Product (DAP is optional, depending on system configuration) can be viewed in a Dose Summary Screen, which can be invoked and displayed on the left monitor. This summary shows the total procedure CAK and DAP with a breakdown on what exposure modes were used, and what fractions of the total dose each mode was responsible for. In GE OEC systems, AKR is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK is calculated from the same, but accumulated over the duration of the procedure. DAP is calculated from the same parameters and also the collimator opening area. The total dose listed on this screen will be incorrect only if the Film or Digital Spot are used during the relevant procedure. All other fluoroscopic modes correctly display the dose within current specifications (i.e. Fluoro, High Level Fluoro, Pulsed, Cine Record). This mis calculation could lead the clinicians to erroneously document the radiation exposure received by the patient

Interim Solution:

At this time a corrective solution for the FlexiView 8800 Mobile C-Arm, OEC® UroView 2800 OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800MD Motorized C-arm System is under investigation. Your facility will be notified as soon as a solution has been identified. In clinical scenarios in which an accurate record of the radiation exposure to the patient is required prior to the system receiving an upgrade, users should contact their GEHC OEC service provider for assistance in determining the actual radiation exposure.

5. System does not boot:

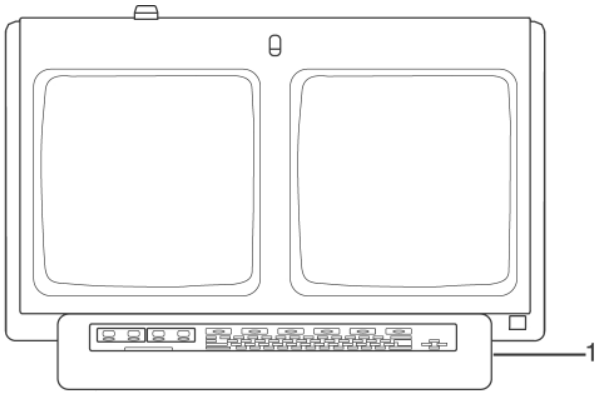
Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800

FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, and OEC® Miniview 6800 may stall during its boot cycle causing a delay in usage. If this condition persists for longer than a minute, the system is stalled.

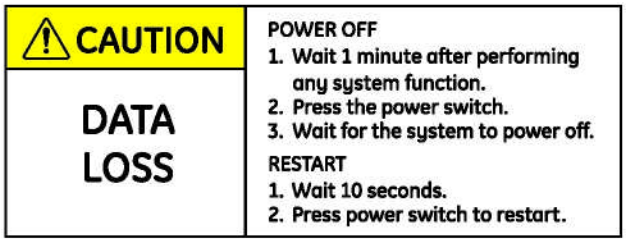
Interim Solution:

Rebooting the system should clear the issue and restore system functionality. When rebooting the system for this issue, before reapplying power, it is important to place the power switch in the OFF position and wait **10 seconds**. Should the system fail to reboot a second attempt at rebooting may be required. These instructions are located in the Operators Guide.

In addition enclosed is a sheet of supplemental stickers, including instructions for attachment that demonstrates the restart steps. These stickers should be promptly attached to your system(s) as indicated below (suggest placement in location #1).



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

GEHC OEC is actively working on solutions that will permanently resolve each of these issues. When solutions become available for those issues that currently do not have a permanent solution, GEHC OEC will contact you and without charge, remedy these issues. For those issues that currently have a permanent fix identified, the GEHC OEC service team will be contacting you to install the correction shortly.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe

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